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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SULLIVAN, DANIEL M

ART UNIT	PAPER NUMBER
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1636

18

DATE MAILED: 10/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/831,907

Applicant(s)

BEAUVILLAIN ET AL.

Examiner

Daniel M Sullivan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-17 is/are pending in the application.
- 4a) Of the above claim(s) 3-8 and 11-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,9,10,14 and 15 is/are rejected.
- 7) ☒ Claim(s) 16 and 17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 July 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

This Office Action is a reply to the "Amendment and Response" filed 21 July 2003 (Paper No. 15) in reply to the Non-Final Office Action mailed 21 March 2003 (Paper No. 13). Claims 3-8 and 11-13 were withdrawn from consideration and claims 1, 2, 9, 10, 14 and 15 were considered in Paper No. 13. Claim 2 was canceled, claims 1, 9, 10, 14 and 15 were amended and claims 16 and 17 were added in Paper No. 15. Claims 1 and 3-17 are pending and claims 1, 9, 10, and 14-17 are under consideration.

Election/Restrictions

This application contains claims 3-8 and 11-13 drawn to an invention nonelected with traverse in Paper No. 11. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Response to Amendment

Rejection of claim 2 is rendered moot by cancellation of the claim.

Drawings

The drawings stand objected to for the reasons set forth on the new PTO-948 enclosed herewith. Applicant is reminded that a proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

Objection to the specification is withdrawn.

Claim Objections

Objection to claims 9 and 10 as informal is withdrawn.

Claim Rejections - 35 USC § 101

Rejection of claim 10 under 35 U.S.C. 101 is withdrawn.

Claim Rejections - 35 USC § 112

Rejection of claims 1, 14 and 15 under 35 U.S.C. 112, first paragraph, as lacking enablement for the full scope of the claimed subject matter is withdrawn.

Claims 9 and 10 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In response to the rejection of record, Applicant has amended the claims such that they are limited to a pharmaceutical composition and method of making a pharmaceutical composition comprising the polypeptides disclosed in the Application. Applicant states, "the Examiner has indicated that the specification is enabling for... 'pharmaceutical compositions or methods of treatment'" (page 9). Applicant asserts that this statement is made in the second

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paragraph on page 8 of the previous Office Action. However, the paragraph cited by Applicant states in full:

To the extent that the claims are directed to pharmaceutical compositions or methods of treatment comprising polypeptides other than those set forth as SEQ ID NO: 1-3, 30-32 and 33-35, the claims are not enabled for the reasons set forth herein above.

Thus, contrary to Applicant's assertion, the Office Action does not indicate that claims limited to the SEQ ID NO: 1-3, 30-32 and 33-35 are enabled, but that claims not so limited are not enabled for reasons already set forth in the Office Action. The discussion in the paragraph bridging pages 8-9 of the Paper No. 13 then sets forth reasons that treatment and pharmaceutical claims are not enabled over any scope. Applicant has not addressed these grounds for rejection; therefore the claims stand rejected under 35 U.S.C. §112, first paragraph, as lacking an enabling disclosure.

Rejection of claims 1, 9 and 10 under 35 U.S.C. 112, second paragraph, as indefinite is withdrawn.

Claim 14 stands rejected under 35 U.S.C. 112, second paragraph, as indefinite for reasons of record in Paper No. 13. Although Applicant has amended the preamble of the claim to recite "candidate hypertensives", the body of the claim is still directed to determining the activity of an anti-hypertensive. Thus, it is still unclear whether the agents used in the method are limited to having predetermined anti-hypertensive activity.

Claim Rejections - 35 USC § 102

Claims 1, 9, 14 and 15 stand rejected under 35 U.S.C. 102(e) as being anticipated by Culp *et al.* U.S. Patent No. 6,075,137.

Applicant argues that the amended claims are no longer anticipated by Culp *et al.* because “Culp *et al.* only has a global homology score of 81.5% based on the sequence of SEQ ID NO: 1” (page 8). This argument has been fully considered but is not persuasive because the sequence disclosed by Culp *et al.* comprises sequence that is 100% identical to the instant SEQ ID NO: 2 and 3. Therefore, to the extent that the claims encompass sequences comprising SEQ ID NO: 2 and 3, Culp *et al.* anticipates the claims.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 10 is rejected under 35 U.S.C. 102(e) as being anticipated by Culp *et al.* (*supra*).

Claim 10 is now directed to a method of making a medicinal product comprising admixing at least one polypeptide according to claim 1 with at least one pharmaceutically acceptable vehicle, wherein the claim is no longer limited to treatment of neurodegenerative diseases or traumas of the spinal chord. As described above, the teachings of Culp *et al.* anticipated the polypeptide according to claim 1, and in the first paragraph in column 13 Culp *et al.* teaches a method of making a medicinal product comprising admixing said polypeptide with

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at least one pharmaceutically acceptable vehicle. Thus, the teachings of Culp *et al.* anticipate the limitations of claim 10.

Allowable Subject Matter

Claims 16 and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448.

The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

dms

Anne-Marie Falk
ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER